TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

IN June 23 88 OUT Oct 31 88

Reviewed by Alex Price Date Oct 31 88

EPA Reg. No. or File Symbol 1730- ON ( 90 )

EPA Petition or EUP No. None

Date Division Received 06-24-88

Type Product(s): I, (D) H, F, N, R, S

Data Accession No(s). 406880405-06-07-08-09-10-11-12

Product Mgr. No. 31 J. Lee

Product Name(s) PINT - SOL SPRAY 19054

Company Name(s) American Cyanamid Company

Submission Purpose Application for Registration, Data review

Chemical & Formulation Spray ( Liquid )

| Active Ingredient(s): | % |
|---|---|
| n-Alkyl ( 60 % C 14, 30 % C 16, 5 % C12 , 5 % C 18 ) dimethyl benzyl ammonium chloride | 0.125 % |
| n-Alkyl ( 68 % C 12 , 32 % C 14 ) dimethyl ethybenzyl ammonium chloride | 0.125 % |

BACKGROUND

The product will be used as a Disinfectant Deodorizer

RECOMMENDATIONS

The data submitted are adequate to place the product tested in the following toxicity category:

| STUDY | TOX CATEGORY |
|---|---|
| Acute Oral | IV |
| Acute Dermal | III |
| Acute Inhalation | III |
| Skin Irritation | IV |
| Eye Irritation | II |
| Sensitization | Negative |

CRP STATUS

This product does/does not require special packaging

LABEL

Revise the precautionary statement-- to read " Causes eye irritation, do not get in eyes on skin or on clothing."

Cat II WARNING

DATA REVIEW

Test Laboratory: Biosearch Incorporated Philadelphia , Pa. 19134

Project # 88-6074A

Acute Oral $LD_{50}$ CFR 81.1

Report date: March 8 88 MRID No. 406894-05

Method of Testing: CFR 81-1

Species: Rats Sprague -Dawley

Sex: Male and females Levels Tested: 5.0 g/kg

Age: Adults No. Animals/dose: 5 m and 5 f

Weights: 200 to 500 g Via: Intubation

Material: Undiluted Observation days: 14

Necropsy: All animals

Procedure

The rats were treated with the material by gavage ( fasted overnight ) and observed for changes in body weight behavioral changes and signs of toxicity . All animals were necropsied

Results:

Signs of Toxicity : Appeared normal

Body Weights : Gained

Mortality : None

Necropsy : Unremarkable

Conclusion: The Acute Oral $LD_{50}$ is greater than 5 g /kg

Core Minimum data

Toxicity Category: IV

Acute Dermal $LD_{50}$ CFR 81.2

Report Date: March 3 88 MRID No. 406894-06

Method of Testing: CFR 81-2

Species: Rabbit, Albino Levels Tested 2.06 g

Sex: Male and female No./animals/dose 5 m and 5 f

Age: Adults Via: Ocluded Patch

Weight: Acceptable Observation days: 14

Material: Undiluted Necropsy: All animals

Procedure The rabbits were tteated with the material in previously clipped areas of the back, under a protective bandage . The bandages were removed and the areas wiped free of material after 24 hours exposure . Observations for behavioral changes, body weights and signs of toxicity were recorded.

Animals that died were necropsied, all animals were sacrificed and necropsied at the end of the study

Result

Signs of Toxicity: Severe dermal irritation , loss of body weight , diarrahea

Mortality: One female at day 12 , after showing emaciation

Body weights: ; Average + Fluctuation in males , females gained

Necropsy: Skin irritation , all males and females , One female , nasal discharge and one diarrahea, dehaydration and death.

Conclusions: The Acute Dermal $LD_{50}$ is greater than 2.06 g/kg

Core Minimum data

Toxicity Category: III

Primary Eye Irritation CFR 81.4

Biosearch Project # MB88-9082 D

Report Date: May 23,88 MRID No.: 406994-07

Method of Testing CFR 81-4

Species: Rabbits Observation days: 14

Dose: 0.1 ml Materials: Undiluted

No. of animals: 6 Via: Ocular instillation

Areas: One eye Necropsy: No

Procedure

The rabbits were treated with the materail instilled into the eye , in the conjunctival sac . The eyes were not washed , the other , non treated eye served as control .

Results: 6/6 Corneal opacity and 6/6 Iritis developed

Conjunctival irritation was 6/6, moderate to severe

Eyes ~~not~~ cleared 2/6 showed corneal opacity till the 7 day, 5/6 conjuntivit-is.

Core Minimum data

Toxicity Category: II

Primary Skin Irritation CFR 81.5

Biosearch Project # 88-6074A

Report Date: Feb 26 88 MRID No.: 406894-08

Method of Testing: CFR 81-5

Species: Rabbits Observation days: 72 hours

No. of animals 6 Material: Undiluted

Dose: 0.5 ml Via: Occluded patch

Areas: Clipped in the back Necropsy: No

Procedure 6 rabbits were treated with the material in intact , previously clipped areas of the back . The treated areas were protected with gauze patch . Wrappings were removed after 4 hours and treated areas washed with tap water .

Results: ~~slight~~ Irritation was found in 6/6 animals

Conclusion: The product is a ~~slight temporary~~ skin irritant

Core Minimum data

Toxicity Category: IV

Dermal Sensitization CFR. 81.6

Biosearch Project # 88-6074A

Report Date: April 4 88 MRID No. 406894-09

Method of Testing: Modified Buehler Method CFR 81-6

Specie: Guinea pigs

Dose: 0.5 ml ,induction /challenge

Challenge dose: 0.5 ml

Areas: ~~Clipped , in the back~~

No. of animals used: 12 males

Material: Undiluted

Observation days: 24 hours after challenge dose

Challenge application day: 3 weeks

Via: Occluded patch

PROCEDURE The material was tested in previously clipped areas of the back of male guinea pigs . . Nine applications were used , Duration , 6 hours and a rest period of at least one day . Total induction application was 9 at which time the animals were allowed to rest for 2 weeks before the challenge dose

Results: Negative results were observed .

In another test ( Biosearch Project # 88-6074A ) using a positive control ( 1-chloro-2,4-dinitrobenzene ) the results were positive

Erythema : ~~None~~

Edema: None

Conclusions: The product is not a dermal sensitizer

Core Minimum data

Toxicity Category: n/a

Acute Inhalation $LC_{50}$ CFR 81.3

Bioserach project # 88-6074A

Report Date: March 22 88 MRID: 406894-11

Method of Testing: CFR 81-3

Species: rats Levels tested: 17.4 mg/l

Sex: Male and female No.animals/dose: 5 m and 5 f

Age: adults Via: Inhalation chamber

Weight: Acceptable Observation days: 14

Material: Undiluted ( aerosol Necropsy: All

Procedure

The rats were treated with the material via inhalation(chamber), for 4 hours and observed for signs of toxicity and changes in body weight

Concentration 17.4 mg/l , nominal; 4.00 mg/l Analytical

0.64 mg/l , respirable

Results

Signs of toxicity: Unremarkable

Mortality: None

Body Weights: Unremarkable

Necropsy: Unremarkable

Conclusions: The Acute Inhalation $LC_{50}$ is greater than 4.00 mg/l

Core Minimum data

Toxicity Category: III

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - II

Antimicrobial Program Branch

EPA Petition or File Symbol 1730-ON

Date Division Received 09-01-88

MRID Nos. 406894-12

Product Manager 31 (Lee)

Product Name Pine-Sol®Spray 19054

Company Name American Cyanamid Company

202.0 Recommendations

202.1 Efficacy Supported By The Data

The submitted data developed by the Modified A.O.A.C. Germicidal Spray Products Test Method are acceptable to support effectiveness of the product as a general disinfectant against Staphylococcus aureus and Salmonella choleraesuis on moderately soiled, hard, non-porous surfaces (5% blood serum) which are thoroughly wet by the spray for a contact time of 10 minutes.

202.2 Efficacy Not Related to Human Health

The submitted data against Aspergillus niger to support efficacy as a fungistat is not considered to be directly related to human health. Therefore, under the efficacy data waiver, such data are not required to be submitted or reviewed.

203.0 Labeling

No Adverse Comments.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

Antimicrobial Program Branch

IN 12-20-88 Out 02-24-89

Srinivas Gowda WEC 2/24/89

Reviewed By Srinivas Gowda Date 02-24-89

EPA Reg. No. or File Symbol 1730-ON

EPA Petition or EUP NO. None

Date Division Received 09-01-88

Type Product General Disinfectant (Household use)

MRID Nos. 406894-12

Product Manager 31 (Lee)

Product Name Pine-Sol® Spray 19054

Company Name American Cyanamid Company

Submission Purpose New Application

Type Formulation Liquid to be used undiluted in Trigger type Mechanical Spraying Device

Active Ingredient(s): %

n-Alkyl (60% $C_{14}$, 30% $C_{16}$, 5% $C_{12}$, 5% $C_{18}$) dimethyl benzyl ammonium chlorides.....0.125

n-Alkyl (68% $C_{12}$, 32% $C_{14}$) dimethyl ethylbenzyl ammonium chlorides.....0.125

200.0 Introduction

200.1 Use(s)

See attached proposed label.

200.2 Background Information

The submission received 09-01-88, is an application for new registration. Efficacy data and proposed labels were provided.

201.0 Data Summary

201.1 Brief Description of Test

Bactericidal test reports by R.T Hennessy, American Cyanamid Company, Shulton Research Division, 697 Route 46, Clifton, NJ 07015, dated 04-09-88 (MRID Nos. 406894-12).

201.2 Test Summaries

a. Bactericidal Tests

1. Method: Modified A.O.A.C. Germicidal Spray Products Test Method.

2. Modifications: The study was modified to include 5% horse serum as organic soil load.

3. Samples:

| Batch No. | Mfg. Dates | Test Dates |
|---|---|---|
| 2620-5A | 02-01-88 | 04-09-88 |
| 2620-5B | 02-01-88 | " |
| 2620-32A | 03-24-88 | " |
| *2620-5B | 04-09-88 | " |

*60 days old sample.

4. Dilution: Undiluted

5. Exposure: 10 minutes at 20°C

6. Subculture Medium/ Neutralizer: Letheen Broth

7. Incubation: 48 hours at 37°C

8.

| Test Bacteria | ATCC No. | Phenol Res. |
|---|---|---|
| Staphylococcus aureus | 6538 | 1:60 |
| Salmonella choleraesuis | 10708 | 1:90 |

9. Survival of Inoculum on Control Carriers After Drying:

| | |
|---|---|
| Staphylococcus aureus | $8.9 \times 10^7$ cfu/ml |
| Salmonella choleraesuis | $1.5 \times 10^5$ cfu/ml |

10. Test Results:

| Organism | Batch No. | # Carriers Tested | # Positives/Total Carriers Tested | |
|---|---|---|---|---|
| | | | Primary | Secondary |
| S. aureus | 2620-5A | 60 | 0/60 | 0/60 |
| | 2620-5B | 60 | 0/60 | 0/60 |
| | 2620-32A | 60 | 0/60 | 0/60 |
| | *2620-5B | 60 | 0/60 | 0/60 |
| S. choleraesuis | 2620-5A | 60 | 0/60 | 0/60 |
| | 2620-5B | 60 | 0/60 | 0/60 |
| | 2620-32A | 60 | 0/60 | 0/60 |
| | *2620-5B | 60 | 0/60 | 0/60 |

11. Conclusions: Satisfactory performance vs. test organisms.